DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

Food and Drug Administration
One Montvale Avenue
Stoneham, Massachusetts 02180
(617)279-1675 FAX: (617)279-1742

April 21, 1997

WARNING LETTER

NWE-06-97W

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Maurice R. Ferre', President and Chief Operating Officer
Visualization Technology, Inc.
30G Sixth Road
Woburn, Massachusetts 01801

Dear Dr. Ferre':

During an inspection of your firm located in Woburn, Massachusetts, on February 25-27, March 4-5, 10-11, and 21, 1997, our Investigators determined that your firm manufactures the *InstaTrak™ System* for image guided sinus surgery as well as Straight and Frontal Sterile Aspirators. These products are devices as defined by Section 20l(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of section 50l(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to have a Quality Assurance Program in place during the manufacture of *InstaTrak™ Systems* IT10020, IT10021, IT1022, IT10024, IT10027, IT10029; Straight Sterile Aspirator Lot JAZ-6263-1; and Frontal Sterile Aspirator Lot JAZ-6263-2.

2. Failure of the Quality Assurance Program to assure the rejection of in-process materials or finished devices. For example, the firm released and distributed *InstaTrak™ Systems* IT10020, IT10021, IT10024, IT10027, IT10028, IT10029, and IT10030 although they failed to meet the automatic registration measurement specified in VTI procedure II-001, Rev 0.0, entitled, "Inspection Instruction, In-process InstaTrak/ConneCTstat System".

3. Failure of the Quality Assurance Program to assure that all quality assurance checks are appropriate and adequate for their purposes and are performed correctly. For example, the firm released and distributed *InstaTrak™ Systems* IT10020, IT10021, IT10024, IT10027, IT10028, IT10029, and IT10030 although they failed to meet the automatic registration measurement specified in VTI procedure II-001, Rev 0.0, entitled, "Inspection Instruction, In-process InstaTrak/ConneCTstat System".

4. Failure to have written manufacturing procedures established, implemented, and in place to assure that devices manufactured by the firm would meet all of their specifications. For example, *InstaTrak™ Systems* IT10020, IT10021, IT10022, IT10024, IT10027, and IT10029; Straight Sterile Aspirator Lot JAZ-6263-1; and Frontal Sterile Aspirator Lot JAZ-6263-2 were all manufactured, inspected, and accepted without having formally established, implemented and controlled procedures in place.

5. Failure to have Device Master Records in place during the manufacture of devices subsequently shipped by the firm. For example, *InstaTrak™ Systems* IT10020, IT10021, IT10022, IT10024, IT10027, and IT10029; Straight Sterile Aspirator Lot JAZ-6263-1; and Frontal Sterile Aspirator Lot JAZ-6263-2 were manufactured without having Device Master Records in place for these devices.

6. Failure to validate significant processes and quality assurance tests utilized by the firm during the manufacture of devices. For example, the firm has not conducted process validation studies to cover the manufacture of the *InstaTrak™ System*, Straight Sterile Aspirators, or Frontal Sterile Aspirators.

7. Failure of the training program to provide personnel with the necessary training to adequately perform their assigned responsibilities. For example, during the course of this inspection employees were unfamiliar with what certain measurement values called out for in the procedures meant.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's

manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

We acknowledge that you submitted a response letter to this office dated April 7, 1997, concerning our Investigators' observations noted on the form FDA 483. We have reviewed your response and have concluded that it is inadequate for the following reasons.

- Your response fails to include an adequate corrective action plan for the Straight Sterile Aspirators, Lot JAZ-6263-1; and the Frontal Sterile Aspirators, Lot JAZ-6263-2. In your response, you state that "the final release of these products was signed on 11/11/96 well after the appropriate procedures were approved and in place." However, the Device History Records for these devices reveal that, although the devices may have been released after the appropriate procedures were in place; they were manufactured well before the appropriate procedures were in place. It is the opinion of FDA that quality cannot be inspected or tested into a finished product.

- In your response, you state that VTI's training records show that the employees responsible for the manufacture and inspection of aspirators and *InstaTrak™ Systems* have received a multitude of training on procedures which will assure that they perform their jobs correctly. Please provide copies of the actual documentation which indicates that this training has occurred.

- Your proposed corrective action plan for the *InstaTrak™ Systems* will presumably attempt to confirm that the devices are within specification. However, this does not change the fact that the devices were manufactured without the proper procedures having been in place. Again, it is the opinion of FDA that quality cannot be inspected or tested into a finished product.

- In your response, you state that *"InstaTrak™* device IT0026 was rebuilt and retested under the implemented Quality Assurance System . . . and that VTI believes that this unit is in compliance with its procedures and GMP's and should remain in commercial distribution". Please provide the necessary documentation to show that this unit was, indeed, produced in accordance with GMP's.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Also, no requests for Certificates For Products for Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction and/or civil penalties.

Please notify this office in writing within I5 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Alyson L. Saben, Compliance Officer, United States Food and Drug Administration, New England District Office, One Montvale Avenue., Stoneham, Massachusetts, 02180.

Sincerely yours,

James A. Rahto
District Director
New England District Office

JAR/GTC/DKE/ALS

cc: R, LR, CF 1225258, ALS, GTC, Nancy Ridley (w/ cover letter and purged WL), HFI-35 (purged WL w/ DD signature), HFR-NE245 (purged), HFA-224, HFR-NE250, HFC-210 (w/ CFN 1225258), HFR-NE12, WL File, HFZ-300, HFC-240 (w/ CFN 1225258), HFZ-306 (FAX to Joy Lazaroff at 301-594-4715), D. Veneziano